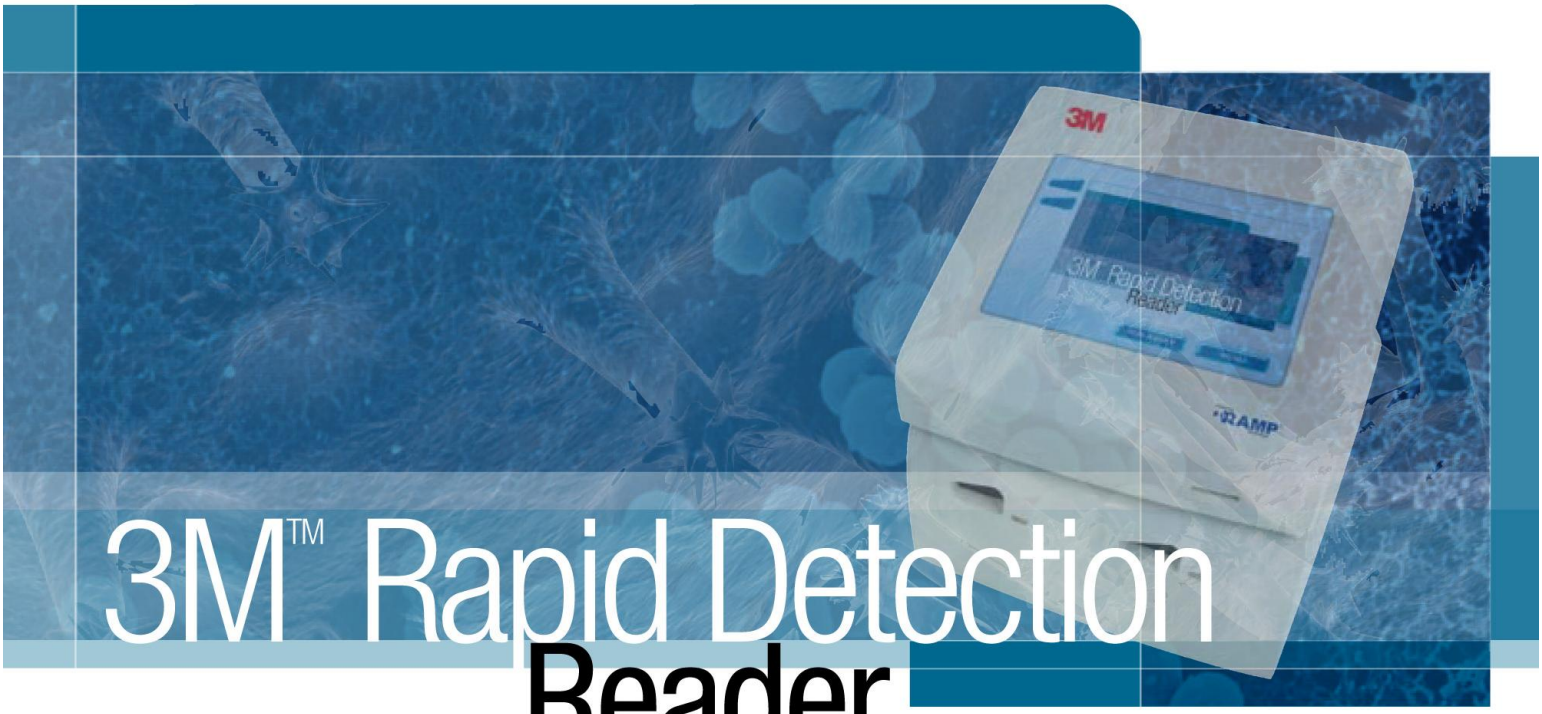
Operator Manual

Version 2.0

Model #3960 – Control Module
Model #3968 – Test Module



3M™ Rapid Detection Reader

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3M™ Rapid Detection Reader Operator Manual

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Warnings and Precautions

Read all contents of this manual prior to use.

The following symbols are used on the 3M Rapid Detection Reader, related components and accessories, or in the text of this user manual:

	WARNING! Indicates a hazardous situation, which if not avoided, could result in death or injury, *e.g.,* fire, electrical shock or explosion.
	WARNING! Hazardous Voltage
	CAUTION. Indicates a situation, which if not avoided, could result in damage to the device. **Consult Accompanying Documents**
	Consult Operator Manual

Summary of Warnings and Precautions

The 3M Rapid Detection Reader and its related devices and accessories are designed to provide safe and reliable service when used according to the instructions provided in this Operator Manual.

The following warnings and precautions should be followed in order to avoid unsafe actions with the 3M Rapid Detection Reader that could potentially result in personal injury or device damage.

WARNING!

To reduce the risk associated with hazardous voltage:

- Unplug the 3M Rapid Detection Reader before cleaning.
- Do not disassemble the 3M Rapid Detection Reader or any of its related components and accessories. The instrument contains no operator-serviceable components.
- Do not immerse any of the 3M Rapid Detection Reader components in any liquid.
- Do not use the 3M Rapid Detection Reader if there is apparent damage to a power cord or power supply.

To reduce the risk associated with potentially infectious patient samples:

- Do not spill specimen or sample fluids on any of the 3M Rapid Detection Reader components or on the outside of the Test Cartridge.
- If a spill occurs, disinfect external surfaces only, using a soft cloth containing a solution of 0.5% bleach, 70% isopropyl alcohol or 70% ethanol.

CAUTION.

To reduce the risk associated with incorrect results:

- 3M Rapid Detection Reader should only be used by trained professionals and operated in accordance with facility policies and procedures.
- 3M Rapid Detection Reader should only be operated in ambient temperature conditions between 15-30°C (59-86°F) and out of direct sunlight.

To reduce the risk of instrument or accessory damage:

- 3M Rapid Detection Reader is not designed to withstand moisture, temperature extremes, severe shock or vibration.
- 3M Rapid Detection Reader is intended for use indoors, located on a stable, stationary surface such as a counter top.
- Do not open any 3M Rapid Detection Reader device enclosures, this will void the warranty.

To reduce the risk associated with environmental contamination:

- Dispose of instrument and accessories in accordance with federal, state, and local requirements.

Introduction

Overview

The 3M Rapid Detection Reader is a rapid immunochromatographic system for performing *in vitro* diagnostic analyses.

The 3M Rapid Detection Reader is comprised of the 3M Rapid Detection Control Module (CM) and the 3M Rapid Detection Test Module (TM). Each Test Module has two ports. Up to three Test Modules are connected to each Control Module providing the user the ability to test 1-6 samples simultaneously. The configuration software and USB flash provided drive allow the user to customize the Reader and maintain the test data. The optional barcode scanner and printer provide ease and accuracy for data entry and record keeping.

Calibration and expiration information for Test Cartridges are input to the 3M Rapid Detection Control Module (CM) through Lot Cards enclosed with the Test Kits.

To perform an assay, the operator places a sample into the well of a Test Cartridge and inserts the Test Cartridge into the 3M Rapid Detection Test Module (TM).

Once the Test Cartridge has been inserted, no further intervention is required. A barcode on the bottom of the Test Cartridge is read to determine the Test Kit lot number. Information loaded with the Lot Card identifies lot specific parameters and expiration date. This ensures that an expired cartridge is not used.

Analysis time is analyte specific and typically less than 20 minutes per sample. Results may be viewed on the 3M Rapid Detection Reader display screen and/or output to the USB flash drive, a printer, or network.

The 3M Rapid Detection Reader only accepts Test Cartridges specified for use with 3M Rapid Detection Test Kits.

The 3M Rapid Detection Reader can operate in either local or network mode. Operator input is accepted from the touch screen or an optional barcode scanner. Stored data including results can be transferred via USB flash drive or sent to a printer or network file.

Intended Use

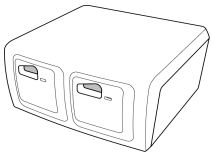
The 3M Rapid Detection Reader is a general use fluorometer that analyzes results produced by immunoassays specified by 3M.

Full operation requires the use of 3M RAPID DETECTION Test Kit. Optional accessories include a printer and barcode scanner.

Unpacking and Setup

Inspect all components carefully. If any damage is visible, notify the carrier and your distributor or 3M to arrange for repair or replacement.

3M Rapid Detection Reader Components

Item	Description	
3M RAPID DETECTION Control Module (CM) Catalog # 3960	3M RAPID DETECTION Control Module Operator Manual Reader Configuration Utility CD Power Supply* USB Flash Drive**	
3M RAPID DETECTION Test Module (TM) Catalog # 3968	3M RAPID DETECTION Test Module Interconnect Cable	

*Only use the approved power cord provided with the 3M RAPID DETECTION CM. A power cord approved for the North American market will be provided with each CM. Outside the North American market, the CM will be supplied with an additional power cord approved for that market.

**Use manufacturer supplied USB Flash Drive. If a USB Flash drive is supplied by the operator, ensure the drive folders match those folders listed in the Manually Transferring / Printing Results or Logs section.

Optional Accessories (Available from 3M)

Optional USB devices supported by the 3M Rapid Detection Reader include a printer and a barcode scanner. Only use the approved USB cables supplied with these devices.

NOTE: Only one of each type of device can be connected to the CM at any given time.

Item	Description	
Printer Catalog # 3965	Printer for self-adhesive roll labels, 2 - 2.5-inches wide. Connects to the CM via USB. Zebra® Technologies TLP 2824™. Consumables: Requires 2.25” W x 3” L Z-Select 4000T labels from Zebra® Technologies (p/n: 800222-305). Requires 57mm x 74m Wax/Resin Ribbon from Zebra® Technologies (p/n: 800132-102). Additional information available at www.zebra.com or 1.847.634.6700.	

Item	Description	
Barcode Scanner Catalog # 3967	Omni-directional, hands-free barcode scanner with cradle for entering Operator and Patient/Sample ID. The barcode scanner is shipped in the correct configuration and is ready for use after connecting to the CM via USB. Symbol Technologies Inc. model LS9208. Additional information available at www.symbol.com, 1.800.653.5350 or 1.631.738.2400.	

3M Rapid Detection Reader Setup

The 3M Rapid Detection Reader is comprised of:

- **3M RAPID DETECTION Control Module (CM)**
  User interface and connectors for all peripherals. Stores and displays test results (view, print, transfer, search, filter/sort)
- **3M RAPID DETECTION Test Module (TM)**
  1 – 3 TMs per CM
  Each TM has two test cartridge ports for performing simultaneous 3M RAPID DETECTION Tests
- **3M RAPID DETECTION Reader Configuration Utility Software (RCU)**
  CD allows customized settings for the 3M Rapid Detection Reader
- **Power supply and interconnect cable**
- **USB flash drive**
  Pre-configured with 4 subdirectories (folders) named: patient, lqc, iqc and log, for use in bi-directional information transfer in a non-networked environment. Also contains “File Converter 1_1.xls”. See Manually Transferring/Printing Results or Logs section.

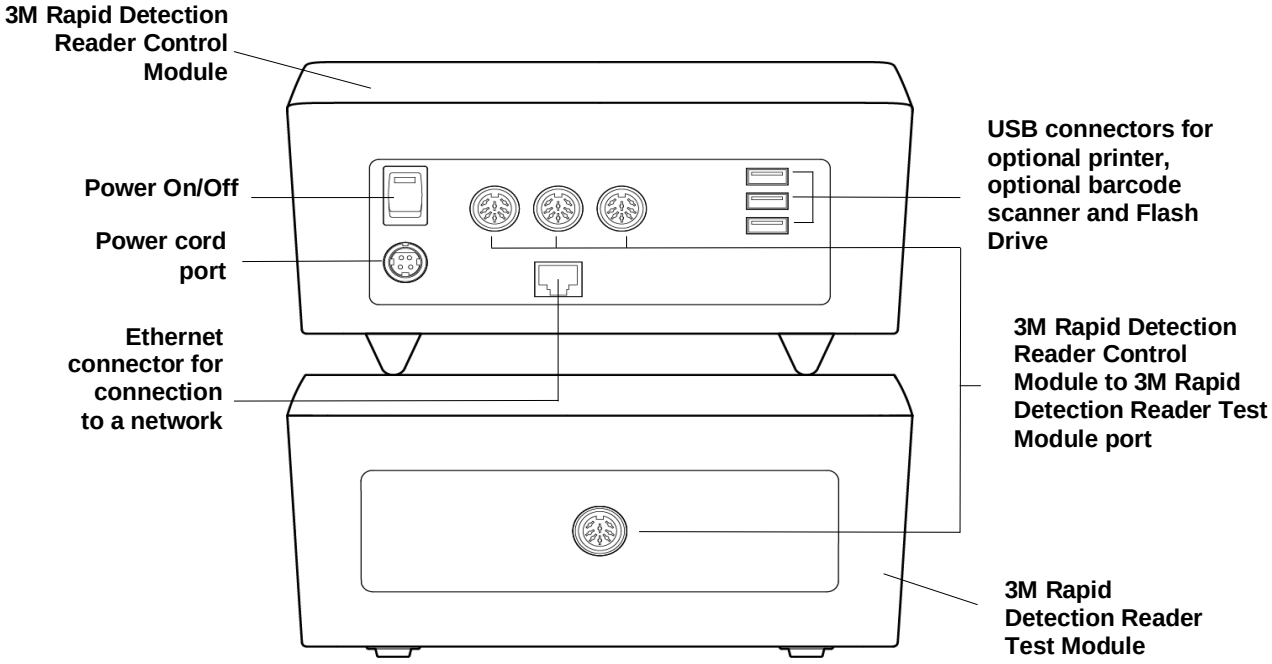
To set-up 3M Rapid Detection Reader:

1. Place the 3M Rapid Detection Reader components on a stable work surface within reach of an electrical outlet. Access to the back of each module is required to connect components.
2. Remove dust protection stickers from TM ports
3. Connect the TM and any optional devices to the CM using the supplied interconnect cable(s).

   Refer to Figure 1 for connector locations.

   Refer to manufacturer’s instructions for optional printer or barcode scanner for additional information on set-up for these accessories.
4. Connect the supplied power cord to the CM. Plug the other end into a wall socket.

Figure 1. 3M Rapid Detection Reader - Rear View Showing Connectors and Power Switch


3M Rapid Detection Reader Control Module
Power On/Off
Power cord port
Ethernet connector for connection to a network
USB connectors for optional printer, optional barcode scanner and Flash Drive
3M Rapid Detection Reader Control Module to 3M Rapid Detection Reader Test Module port
3M Rapid Detection Reader Test Module

NOTE:

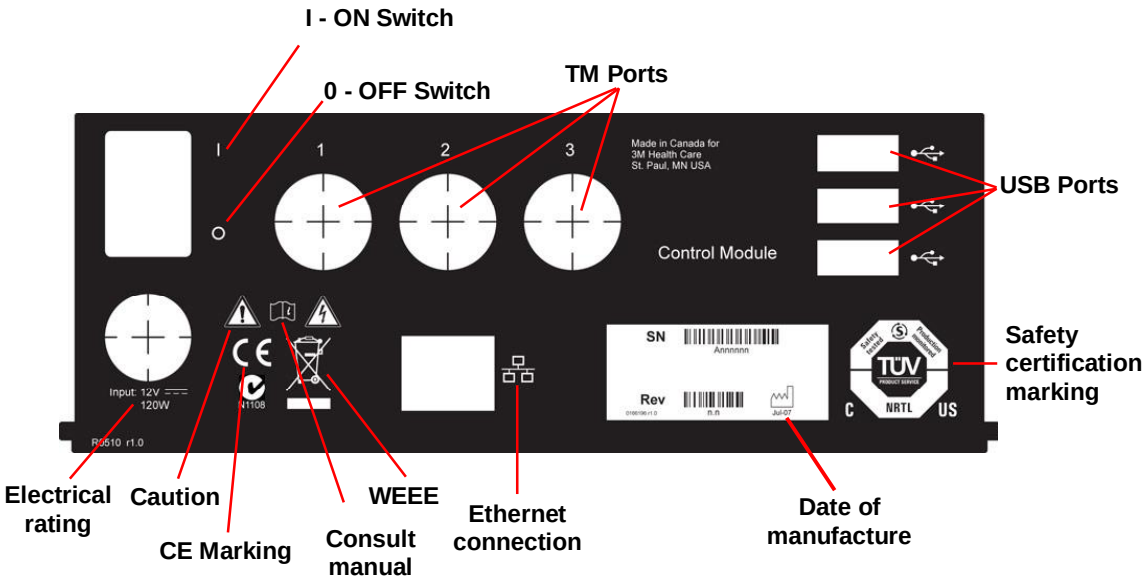
- 1, 2, or 3 TMs can be connected to each CM
- TMs can be stacked
- CM can be placed on top of the TM
- Do not place anything on top of the CM.

CAUTION.

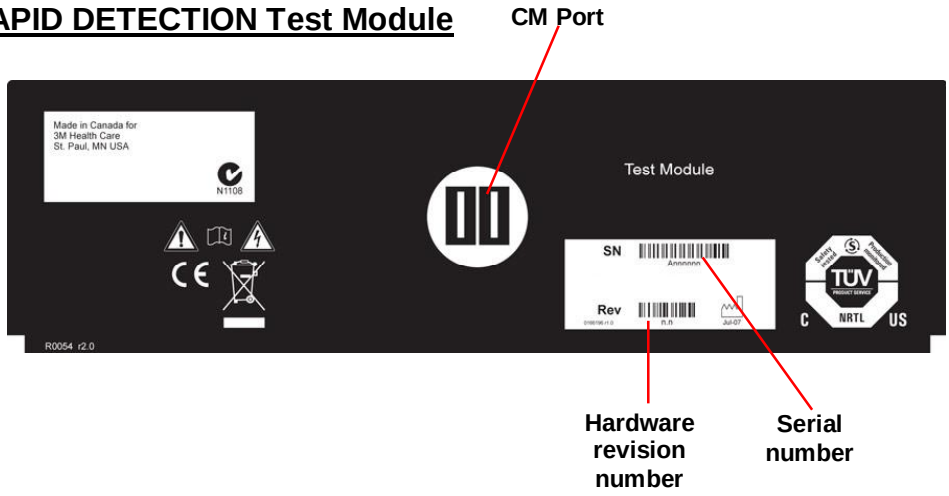
Do not stack CM on top of TM unless all four feet are in place.

Figure 1a. 3M Rapid Detection Reader – Rear view panel labels and description

3M RAPID DETECTION Control Module

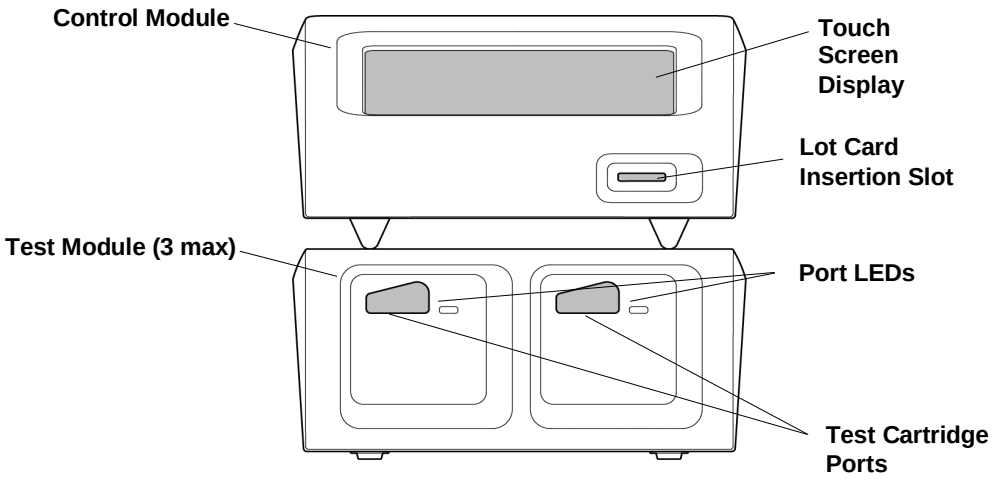


3M RAPID DETECTION Test Module



3M Rapid Detection Reader (MODULES)

Figure 2. 3M Rapid Detection Reader Features - Front View

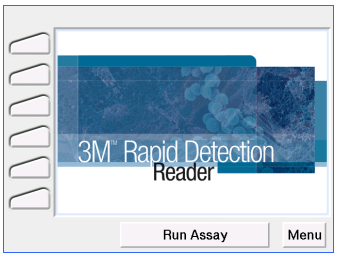


Turning on the 3M Rapid Detection Reader

The power On/Off switch is located on the rear panel of the CM (Figure 1). When the power is switched on, the 3M Rapid Detection Reader performs a number of internal self-tests, including IQC, to ensure the system is operating within specifications. For additional information, refer to Running Quality Control section.

When switched ON, the LEDs on the front of the TM illuminate blue. When the power-on sequence is complete, the **Home** screen is displayed (Figure 3). The power-on sequence takes approximately 1 minute.

Figure 3. Home



Once the **Home** screen is displayed, selections can be made by touching the appropriate prompt on the display (*i.e.,* Run Assay to initiate an assay, or Menu to go to the **Main Menu** screen (Figure 4)). The display is touch-sensitive and can accept input from a bare/gloved finger or a blunt stylus.

The 3M Rapid Detection Reader can be operated immediately after set-up using the pre-programmed default settings. The date, local time and some settings can be edited manually through the Settings menu on the CM touch screen. Most settings can be edited using the **Reader Configuration Utility (RCU)** supplied with the CM. For additional information on editing user settings, refer to Managing Settings and Editing Settings Using the Reader Configuration Utility (RCU).

CAUTION.

Pens or other sharp instruments will damage the touch screen.

Display Icons

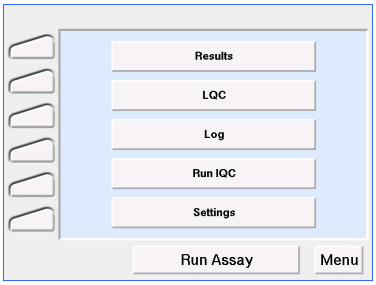
The left hand column of the screen displays an icon for each available port. Touching these icons leads to a full screen display of the status of that port.

The lower left corner of the display screen, below the port icons, displays LQC, Printer and Communication warning icons.

The meaning of the displayed icons is as follows:

Icon	Meaning
	Port Idle
	Port Busy
	Assay Timing
	Sample processing and cartridge movement
	Error – (HRB for example only). For detailed information see Troubleshooting
	Aborting assay, cartridge ejecting, error message to follow
(Non-selectable)	Liquid Quality Control Warning See Running Quality Control
(Non-selectable)	Liquid Quality Control Expired Warning See Running Quality Control
(Non-selectable)	Printer Error See Troubleshooting
(Non-selectable)	Data Transfer Error See Transferring Results or Troubleshooting

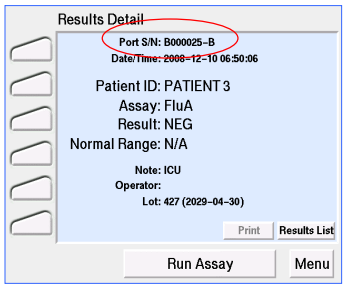
Figure 4. Main Menu



Port Identification Nomenclature

Ports on the 3M Rapid Detection Reader are identified by a multi-character nomenclature system. The first set of characters is the serial number of the TM; the last character is a letter (A or B) referring to the left (A) or right (B) port for a particular TM. This is displayed at the top of the screen (Figure 5) when the port icon is touched or if there is an IQC port error and in the IQC results log.

Figure 5. Port Identification



Performing an Assay

WARNING!

To reduce risk to the operator:

- Observe local protocols and appropriate precautions in the collection, handling, and disposal of specimens.

CAUTION.

- When entering data via the CM touch screen (*e.g.*, Sample/Patient/User ID), enter characters one at a time as failure to do so may result in erroneous data entry.
- Be familiar with all of the instructions in the Test Kit Package Insert including Warnings and Precautions prior to performing an assay.

Using Lot Cards

The Lot Card provides lot specific information and the expiration date for each Test Kit and is only required to be read once for each Test Kit lot. Prior to performing any assay, insert the Lot Card for that Test Kit lot into the Lot Card Insertion Slot (Figure 2). The CM can store information from 50 different Test Kit lots. If the maximum is exceeded, the oldest entry is overwritten.

CAUTION.

To avoid damaging the Lot Card:

- Do not touch the contact pads on the Lot Card.
- Store the Lot Card in the anti-static pouch provided.

To use the Lot Card:

1. Remove the Lot Card from the anti-static pouch.
2. Hold the Lot Card so that the arrow is on the top side and pointing away.
3. Insert the Lot Card, contact end first, into the slot located on the front of the CM.
4. The display provides status messages: **Reading Lot Card, Complete**, **Lot ID: XXX**, **Remove Lot Card**.
5. Remove Lot Card and store in its original pouch.
6. If an error message is displayed, or if there is no response to insertion of a lot card, refer to the Troubleshooting Section.
7. Keep the Lot Card for the life of the Test Kit.

Starting an Assay

NOTE: The default setting of the 3M Rapid Detection Reader does not require an Operator ID or password. These login requirements can be edited via the **Edit Operator** settings menu or **RCU** (See Managing Settings). If using default settings, Figure 6 will not appear.

If the following Liquid Quality Control warnings LQC or LQC appear, refer to Running Quality Control.

NOTE: The message **Lot # XXX Not Found**, **Insert Lot Card or Cancel** will be displayed if a Test Cartridge is inserted and the Lot Card data is not stored in the CM. The Lot Card must be inserted within 40 seconds or the assay will be aborted. Touch **OK** to return to the **Home** screen.

1. Touch **Run Assay**. If prompted, enter Operator ID and/or Password (Figure 6) using either the touch screen or the barcode scanner. To accept the displayed information, touch **Accept**. NOTE: The Operator ID and Password entries are case-sensitive.
2. When prompted, enter the Patient ID/Sample ID using either the touch screen or barcode scanner (Figure 7). Touch **Accept**.
3. When prompted to **Add Sample & Insert** the Test Cartridge, the LED on a free port of the TM will flash blue and the corresponding port icon on the display will illuminate blue (Refer to Test Kit Package Insert for detailed instructions on sample handling).
4. Prepare Sample and Test Cartridge as stated in the Test Kit Package Insert and insert Test Cartridge into the flashing port.

   If the cartridge is not inserted within 5 minutes of the **Add Sample & Insert** prompt, the system will time-out. Touch **OK** to return to the Main Menu.

   NOTE: The Test Cartridge must be inserted into the TM within ~30 seconds of sample application. Otherwise, **FAIL** will be displayed in the port icon and the assay will be aborted.

Figure 6. Operator Entry

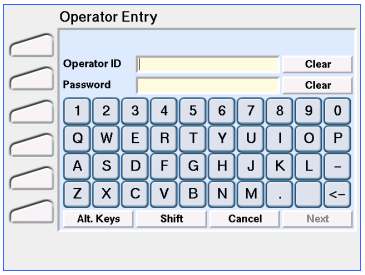
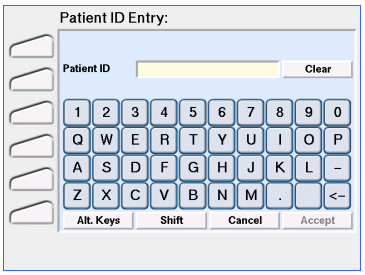


Figure 7. Patient ID Entry



Do not use excessive force when inserting the Test Cartridge. The TM will guide the Cartridge into place.

NOTE: If the cartridge won't fit or won't enter the cartridge port, clear the cartridge port of any obstruction or blockage.

Once the **Cartridge Inserted** message clears, the previous screen is displayed and the active port icon

shows a timer that counts up until sample flow is detected, then counts down until the assay is complete.

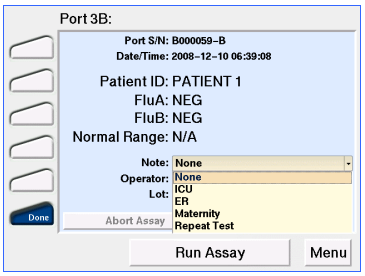
Another assay can be started once **Assay Initialization** is complete by touching **Run Assay**.

5. To check the assay progress, touch the port icon. The details of the assay will be displayed. Touch **Exit** to return to the previous screen. Touching **Abort Assay** will cause the cartridge to be ejected and a Failed Assay to be recorded in the **Events Log**.
6. When an assay is complete, the Test Cartridge is ejected and the corresponding port icon displays

. To view the test details touch the icon.
7. Before removing the Test Cartridge from the TM, a predefined note can be added to the result from the drop down menu on the **Result Details** screen (Figure 8). Once the Test Cartridge is removed, a note cannot be added or changed.

   Up to 10 notes can be defined using the RCU (Refer to Editing Settings Using the Reader Configuration Utility section).
8. Remove the Test Cartridge and discard according to local hazardous waste policy.

Figure 8. Results, prior to cartridge removal



Running Quality Control

Two types of quality control test records are stored by the 3M Rapid Detection Reader:

- **LQC** (Liquid Quality Control) - external surrogate sample test results.
- **IQC** (Internal Quality Control) - self-diagnostic test results including a check of the power supply voltage, system memory, cartridge transport system, cartridge barcode sensor, LED function, and incubator function for heated assays.

Running LQC

1. From the **Main Menu** screen (Figure 4) touch **LQC**. The **LQC – Assay List** screen will open (Figure 9). This screen will display the entire list of assays sorted in ascending order by the Time to Expiry before assay lockout as displayed in the LQC Expiration column. If LQC is due, this column will display "Run x of y levels" where x is the number of levels required and y is the number of defined LQC levels for that assay. Both the number of levels required and the available defined levels are set using the RCU.

   The LQC status column shows the requirements for any LQC levels that have failed. If any LQC fails, that specific control level must be run successfully prior to proceeding with a patient's test. If the maximum number of Failures before LQC Lockout is reached, this column will display "LQC Lockout".

   NOTE: The assay list is defined in RCU. Any new assays added in the RCU or through the CM will default to LQC disabled and will be listed with N/A in the LQC Expiration column. Refer to the RCU Help Manual for further instruction.

Figure 9. LQC - Assay List

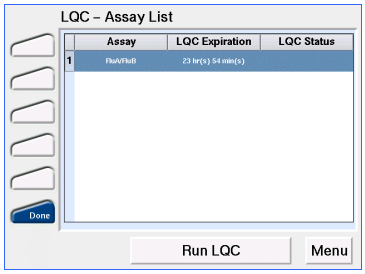
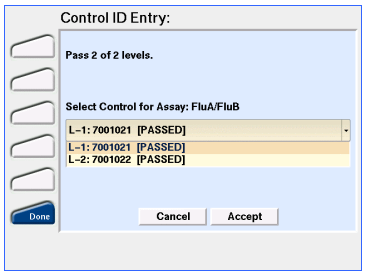


Figure 10. Control ID Entry



2. Select the assay for which LQC will be performed. Touch **Run LQC**. If prompted, enter Operator ID and/or Password using either the touch screen or the barcode scanner. To accept the displayed information touch **Accept**.

   NOTE: Both the Operator ID and Password are case-sensitive.

3. When prompted (Figure 10), select the appropriate Control ID using the drop down menu. Touch **Accept.**

   NOTE: If LQC has failed for the assay selected, the number of LQC attempts allowed prior to assay lockout is displayed.

4. When prompted to **Add Control & Insert** the Test Cartridge, the LED on a free port of the TM will flash blue and the corresponding port icon on the display will illuminate blue (Refer to Test Kit and Quality Control Package Inserts for detailed instructions).

5. Prepare Test Cartridge as per Test Kit Package Insert and insert Test Cartridge into the flashing port.

   If the cartridge is not inserted within 5 minutes of the **Add Control & Insert** prompt, the system will time-out and return to the Main Menu.

   NOTE: The Test Cartridge must be inserted into the TM within ~30 seconds of sample application. Otherwise, **FAIL** will be displayed in the port icon and the assay will be aborted.

Do not use excessive force when inserting the Test Cartridge. The TM will guide the Cartridge into place.

Once the **Cartridge Inserted** message clears, the previous screen is displayed and the active port icon

shows a timer that counts up until sample flow is detected, then counts down until the assay is complete.

NOTE: Touching **Run Assay** or **Run LQC** will start another assay/LQC and the test sequence will begin again using a different available port. The assay progress can be checked by touching the port icon. Touch **Exit** to return to the previous screen.

6. When an assay is completed, the corresponding port icon displays

and the Test Cartridge is ejected. Touch the icon to view the test details.
7. Remove the Test Cartridge and discard according to local hazardous waste policy.

LQC Icons

Icon	Meaning
	LQC will be due shortly. Appears when the LQC timer for an assay has less than the user defined % of time remaining until lockout.
	LQC has expired for one or more assays. If icon is displayed, the **Assay Status Warnings** screen (Figure 11) will display upon touching the **Run Assay** button. Touch **Continue** if the desired assay is not listed. A limited number of overrides can be configured via the RCU. If overrides are available, touch **Continue** to override lock out (*i.e.,* perform a patient test after LQC is due). The decision to use an Override will be confirmed (Figure 12). Once all overrides have been used, LQC must be performed prior to any further patient testing. If an assay with no overrides is inserted into the TM, an **LQC Overdue, Assay Locked** warning will display and the assay will be aborted.

Figure 11. Assay Status Warnings

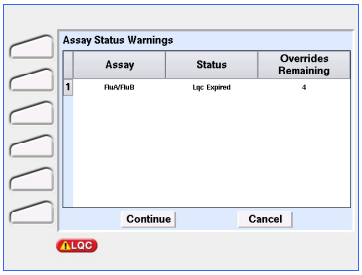
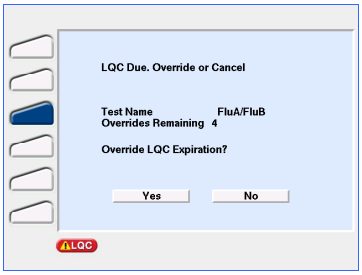


Figure 12. Override Confirmation



NOTE: These warnings are display only and are not selectable. To determine the assay(s) for which LQC is due, view the **LQC – Assay List** (Figure 9).

NOTE: If there is more than one level of LQC defined for an assay, and LQC has expired for this assay, the LQC timer will be reset to the time at which the earliest LQC level passes in the set. *e.g.*: Two levels of QC are required, Level 2 passes LQC but Level 1 fails; once Level 1 is repeated and passes, the "Time to Expiry" column in the LQC menu will display the count down from the time when Level 2 passed.

Running IQC

IQC runs automatically every time the 3M Rapid Detection Reader is turned on. IQC can also be initiated manually or configured to run at predefined intervals. IQC takes less than 1 minute to complete.

When IQC is initiated, the appropriate tests are performed on each port in each attached TM. IQC verifies the power supply voltage, system memory, cartridge transport system, LED function and incubator function for heated assays. During IQC the system also determines system power, verifies the system clock and verifies the Reader calibration.

Should there be a test in progress in a port, IQC will begin for that port once the test cartridge is removed on assay completion. Results of the IQC are stored for each cartridge port in the IQC results database.

To run IQC manually:

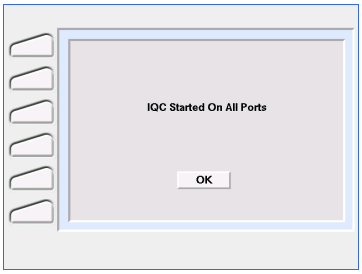
1. From the **Main Menu** screen (Figure 4), touch **Run IQC**. If prompted, enter the Operator ID and/or Password using either the touch screen or barcode scanner. To accept the displayed information, touch **Accept**. The **IQC Status** screen is displayed (Figure 13).

   NOTE: Both the Operator ID and Password are case-sensitive.

   IQC is started on all idle ports and will automatically start as ports become free.

2. Touch **OK** to return to the Main Menu. If IQC fails, the TM port LED illuminates red, the port icon turns red and the failed port can no longer be used. *e.g.*,

Figure 13. IQC Status



To run IQC automatically:

To run IQC automatically at predefined intervals, the Reader is configured using the RCU or the CM.

To configure the Reader to run IQC at defined intervals through the RCU, refer to Editing Settings Using the Reader Configuration Utility (RCU) section.

To configure the Reader to run IQC at defined intervals through the CM, refer to the Managing Settings section.

Working with Results and Logs

The 3M Rapid Detection Reader can store up to 900 results (300 assay results, 300 LQC results and 300 IQC results). When the CM database is full, the oldest result is over-written. Dual analyte assay results are stored as two separate patient records. IQC results are stored separately for each individual test port.

In manual transfer mode only (*i.e.,* when 3M Rapid Detection Reader is not connected to a network), the warning "Database Almost Full, Backup Data" will be displayed when the assay or LQC result databases have less than 20 spaces left. This message will continue to be displayed until the database is cleared.

In auto transfer mode, only new results that have not been previously transferred are transferred during an upload. Data is not deleted from the CM upon transfer.

The 3M Rapid Detection Reader can store up to 500 Log records (including system power up, upload/download of data, assay and LQC errors). When the database is full, the oldest result is over-written. A warning message is **not** displayed when the Log database is full.

Viewing Saved Results

1. From the **Main Menu** screen (Figure 4), touch **Results**. If prompted, enter Operator ID and/or Password using either the touch screen or the barcode scanner. To accept the displayed information, touch **Accept**.

   NOTE: Both the Operator ID and Password are case-sensitive.

   The screen displays a list of all **Assay Results** (Figure 14). The most current assay result is the first listed. For each assay result, the Patient ID, assay name, result value, and date/time is displayed.

   To view a list of LQC or IQC results, touch the circle next to the words **LQC Results** or **IQC Results** (in the display header) to specify the type of results to be viewed. The list of results will be displayed.

2. To view the details of a particular result, touch the result, and then touch **View**. To return to the result list, touch **Results List**.

Figure 14. Assay Results

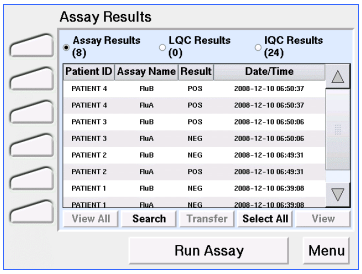
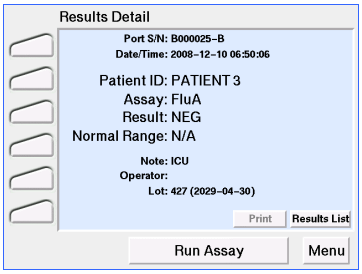


Figure 15. Results Detail



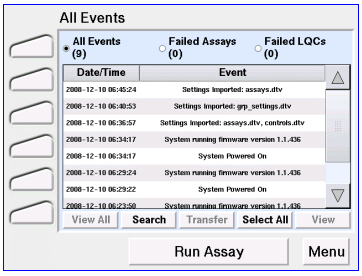
Viewing Saved Logs

1. From the **Main Menu** screen (Figure 4), touch **Log**. If prompted, enter Operator ID and/or Password using either the touch screen or the barcode scanner. To accept the displayed information, touch **Accept**.

   NOTE: Both the Operator ID and Password are case-sensitive.

   A list of all events will be displayed (Figure 16). The most recent event is listed first. For each event, the Date/Time is displayed. To view a list of assay or LQC errors only, touch the circle next to the words **Failed Assays** or **Failed LQC** (in the display header) to specify the type of results to be viewed. The list of events will

Figure 16. All Events



be displayed.

To view the details of a particular event, touch the event, and then touch **View**.

2. To return to the event list, touch **Events List**.

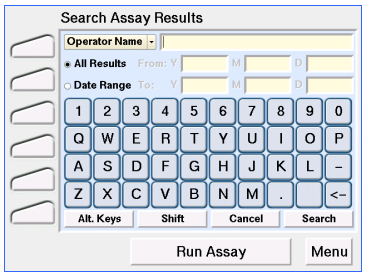
Searching Results

Result Type	Search Options		
Assay	Operator Name	Sample/Patient ID	Assay Name
LQC	Operator Name	Control ID	Assay Name
IQC	Operator Name	Port	

1. From the Assay (or IQC or LQC) Results screen, touch Search to open the Search Assay Results screen (Figure 17).
2. Use the drop down arrow € on the Operator Name to change the search parameter.
3. Use the touch screen or barcode scanner to enter the desired value to search. Touch Alt. Keys or Shift to display extended character sets.

   NOTE: Enter the first few characters or the entire name or ID to be found.
4. Touch either All Results or Date Range. All Results is the default setting. When Date Range is touched, the From/To Y M D fields become active. Enter the desired dates in YYYY MM DD format.

Figure 17. Search Assay Results



5. Touch **Search** to generate a list of results based on the search criteria entered or touch **Cancel** to clear the search criteria and return to the main **Results** screen.
6. If no results matching the search criteria are found, **Empty Search** will be displayed.
7. When viewing the records for a particular search, touch **View All** to return to viewing the complete Results list.

Searching Logs

Log Type	Search Options		
All Events	Operator Name	Event Text (enter any part of field, not case-sensitive)	
Failed Assays	Operator Name	Sample/Patient ID	Assay Name
Failed LQC	Operator Name	Control ID	Assay Name

Follow the directions above for Searching Results.

Manually Transferring / Printing Results or Logs

Results (assay, patient or IQC) that have been selected on the **Results** screen can be transferred to a printer, USB flash drive or to a network. It is important to note that the user should manually delete the results from the Reader after manual transfer or they will be transferred again, unless a specific range of results is selected when the next manual transfer is performed.

Log events (All, Failed Assays or Failed LQC) that have been selected on the **Events** screen can be transferred to a USB flash drive or to a network. Only Failed Assays and Failed LQC can be printed from the CM.

NOTE: A single USB flash drive can be used to transfer results from all Readers as the file names start with their respective control module serial numbers. The USB flash drive must be preconfigured with 4 subdirectories (folders) named: patient, lqc, iqc and log, for this use.

CAUTION.

Do not remove the USB flash drive from the control module while data is being transferred.

1. From the **Assay Results** (Figure 14) or **All Events** (Figure 16) screen, select record(s) by touching the desired record(s). Touch **Transfer** to open the **Results** or **Events Transfer** screen (Figure 18 shows results transfer as an example).

   IQC and LQC results or failures can be transferred or printed in the same manner from their respective screens.

2. On the **Results** or **Events Transfer** screen, touch **Print**, **USB** or **Network** as desired. On the **Events Transfer** screen, touch **USB** or **Network** as desired. Only options for which the connections are available will be functional.

3. Confirm the transfer by touching **Confirm**. Touch **Cancel** to abort transfer. (Figure 19)

   When the transfer is complete, touch **OK** and the **Results** screen (or **Events** screen) will be displayed. If transfer fails the warning icon and a failure message are displayed, touch **OK** to return to **Results** or **Events** screen (the screen depends on the previous context, *e.g.,* if transferring LQC results, then LQC Results screen will be shown).

   Once results have been transferred, File Converter 1_1.xls on the supplied USB flash drive may be used to convert the data files to an Excel format.

Figure 18. Results Transfer

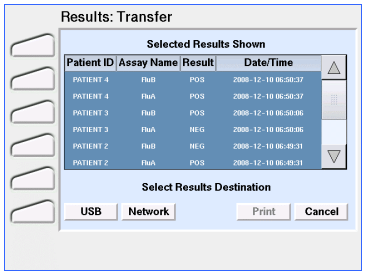
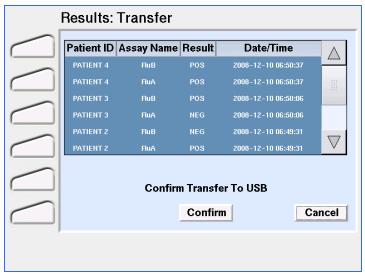


Figure 19. Result Transfer Confirmation



Open the file “File Converter 1_1.xls”, enable Macros, and follow the directions on the screen.

You will be prompted to save the Excel-formatted file.

NOTE: File Converter 1_1.xls must be used for this purpose. Data will not be formatted properly if an earlier version of File Converter.xls is used.

Managing Settings

The 3M Rapid Detection Reader can be operated immediately after set-up using the pre-programmed default settings. Each Reader also has customizable features which can be configured to enhance its functionality and data management capability. Customizable features include LQC timer, Operator ID and password, and data transfer options (USB, print, network). Some of these features can be configured in the CM **Settings** menu. In the default configuration, these settings can only be viewed or changed by an operator with Supervisor access. Most feature configurations are set using the Reader Configuration Utility (RCU) by a Full Access User. For instruction on configuring settings on the CM, refer to **Edit Settings** and **Edit Operators**. For instructions on configuring settings using the RCU, refer to **Editing Settings Using the Reader Configuration Utility (RCU)**.

Feature (See Detailed Descriptions Below)	Full Access User Edit on RCU	Supervisor Edit on CM
Assay defaults	√	
LQC	√	
Update / Upload Features	√	
Printer Settings	√	
Login Requirements	√	√ (limited)
File Settings	√	√
Menu Idle / Timeout		√
Date / Time (without Network Time Protocol – NTP)	NTP only	√
Language		√
Auto IQC Interval	√	√
Network Transfer Timers		√
Sound		√

Accessing the Settings Menus

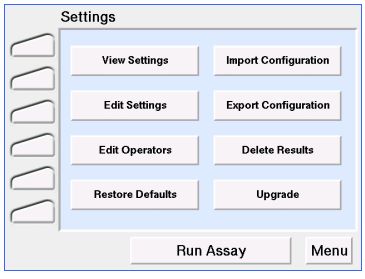
From the **Main Menu** (Figure 4), touch **Settings**. Access to the Settings menu is Operator ID and Password protected. The default login for access to the Settings menus is:

Operator ID: **SUPERVISOR**

PASSWORD: **PASSWORD**

Both entries are case-sensitive. To provide additional security, it is highly recommended that this login be changed.

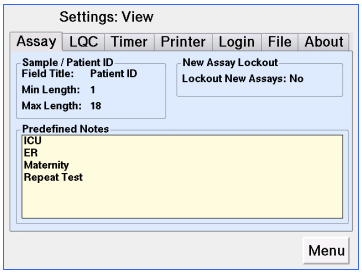
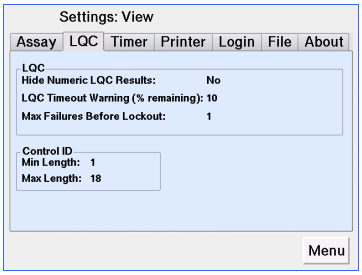
Figure 20. Settings Menu



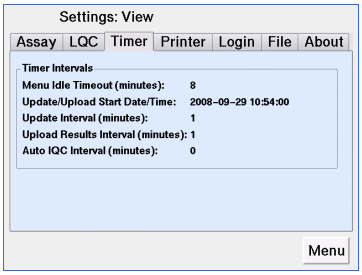
NOTE: The default privilege access to the Settings menu is Supervisors only (Figure 25). The privilege access to this menu can only be changed via the RCU. In the default setting, any operator defined in the Operator List as Supervisor [Operator Type] is able to access the Settings menu. Refer to Managing Operators for additional information.

Touch **View Settings** from the **Settings** menu (Figure 20). This will open the screen shown in Figure 21. Settings in the **View Settings** screen cannot be edited.

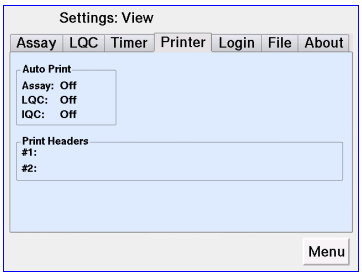
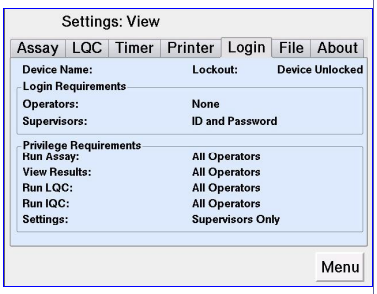
Settings: View Tabs

Tab	Screen
Assay Edit through RCU only. **Sample/Patient ID** Purpose: Define the field name as Patient ID or Sample ID. Default: Patient ID. String length can be set from 1 to 18. Default: Min Length 1, Max Length 18. **New Assay Lockout** Purpose: Define ability of operators to perform assays not in the assay list. The assay list is displayed on the **LQC-Assay List** screen (Figure 9). Set as either Yes or No. Yes: End users cannot run any assays that are not on the RCU defined assay list. No: End users can run any 3M Rapid Detection Reader assay. Default: No. **Predefined Notes** Purpose: Define up to 10 notes that an operator can attach one of these notes to each patient test result prior to removing the Test Cartridge from the TM. The Note becomes part of the result record when the Cartridge is removed from the TM. **NOTE:** The predefined note can be up to 20 characters in length. Make sure the note entered through the RCU is less than or equal to 20 characters in length.	**Figure 21. Settings: View Assay Tab** 
LQC Edit through RCU only. Default: Timer Reset (hours) = 0, LQC will not time-out. **Hide Numeric LQC Results** Purpose: To Hide LQC results and report only PASS/FAIL Yes: Pass/Fail will be displayed in place of results. No: Actual result will be displayed. Default: No. **LQC Timeout Warning (% remaining)** Purpose: Define the percentage of the LQC interval remaining (if LQC Timer is set in RCU) before LQC expires for any assay. Default: 10%.	**Figure 22. Settings: View LQC Tab** 

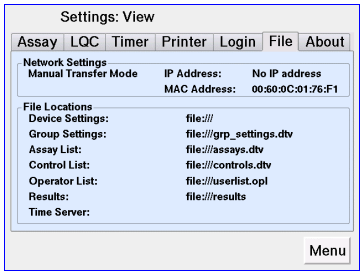
Settings: View Tabs

Tab	Screen
LQC *continued* **Max Failures Before Lockout** Purpose: Define the number of LQC failures allowed before the assay is Locked Out when LQC Timer is set in RCU. LQC Failure count is reset upon successful completion of LQC. Can be set from 1-9. Default: 9. **Control ID** Purpose: Define control IDs. Default: Min length 1, Max length 18.	
Timer The ability to edit the settings of the TIMER tab varies by item and is defined below. **Timer Intervals** **Menu Idle Timeout** Edit on CM. Cannot edit through RCU. Purpose: Define the amount of idle time before the 3M Rapid Detection Reader returns to the **Home** screen. Range: 1 -10 minutes. Default: 5 minutes. **Update/Upload Start Date/Time** Edit through RCU only. The date and time used to calculate the start of the following intervals. **Update Interval** Edit through RCU only. Purpose: Interval at which the Reader checks for changes to settings in a networked environment. Disable by entering 0. Range: 0 – 1440 minutes. Default: 1. **Upload Results Interval** Edit through RCU only. Purpose: Interval at which the Reader sends changes or additions to the result and event logs in a networked environment. Disable by entering 0. Range: 0 - 1440 minutes. Default: 0 (Disabled).	**Figure 23. Settings: View Timer Tab** 

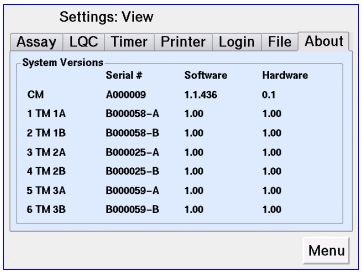
Settings: View Tabs

Tab	Screen
Timer *continued* **NOTE:** Only new results that have not been previously transferred are transferred during an upload. Data is not deleted from CM upon transfer. When the CM database is full, the oldest result is over-written. **NOTE:** It is important that the upload interval be set to ensure data capture and transfer prior to records being overwritten. **Auto IQC Interval** Edit on CM and through RCU. Purpose: The interval between automatic IQC self-diagnostics in either local or networked environment. Disable by entering 0. Range: 0 – 1440 minutes. Default: 0 (Disabled).	
Printer Edit through RCU only. **Auto Print** Purpose: Defines if automatic printing is enabled. Settings are independent for assay, LQC and IQC results. On: Result will automatically print upon completion. Off: Result will not print automatically. Default: Off. **Print Headers** Purpose: Define customized print header information that will be visible on every printout.	**Figure 24. Settings: View Printer Tab** 
Login Edit through RCU only. **Device Name** Purpose: Define name assigned to the device. Default: Blank. **Lockout** Purpose: Disable Reader. Device Locked: Assays cannot be run. Device Unlocked: Assays can be run (Default).	**Figure 25. Settings: View Login Tab** 

Settings: View Tabs

Tab	Screen
Login *continued* **Login Requirements** Purpose: Define login requirements independently for Operators and Supervisors requiring None, ID and Password, ID only or Password only. If None, an Operator ID cannot be entered when running assays. Default: Operators – None, Supervisors – ID and Password. **Privilege Requirements** Purpose: Defines the access privileges for each level user. All Operators: Operators and Supervisors have access. Supervisor only: Only Supervisors have access. Default: Default settings are shown in Figure 25**.**	
File Edit through RCU only. Purpose: Define network settings for the Reader **Network Settings** Manual Transfer mode: 3M Rapid Detection Reader is being used without being connected to a shared network. IP Address: Automatically assigned when the 3M Rapid Detection Reader is connected to a network and in Auto transfer mode. MAC Address (Machine Address Control): This is a static address that represents the identity of the 3M Rapid Detection Reader. Default: Manual Transfer Mode. **File Locations** Purpose: Define the directory where the 3M Rapid Detection Reader files reside, defined when implementing connectivity through the RCU. Please consult the local IT administrator and the online help for guidance on the use of these settings.	**Figure 26. Settings: View File Tab** 

Settings: View Tabs

Tab	Screen
About Purpose: This tab displays the details the Serial Number, software and hardware versions of the 3M Rapid Detection Reader System. This information will assist in discussions with Technical Support.	**Figure 27. Settings: View About Tab** 

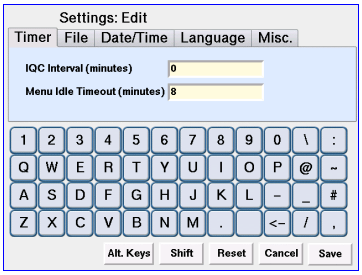
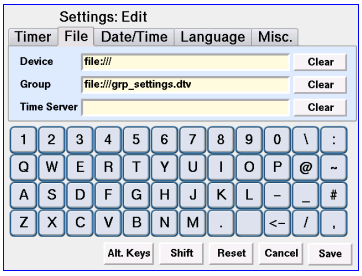
Edit Settings

From the Main Menu select **Settings**. Only a Supervisor, when in the default systems configuration, can access the **Settings** menu. (Refer to **Access the Settings Menus** for additional information.) Touch **Edit Settings** on the **Settings** menu, and use the tabs to select those settings to be changed.

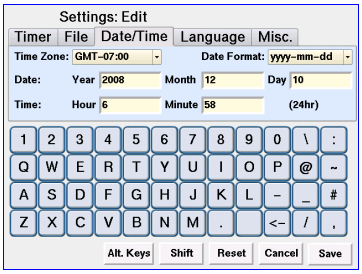
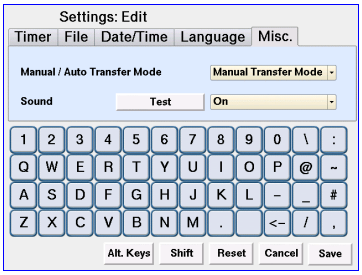
On all the **Settings: Edit** dialogs:

- Use the touch screen or dropdown lists to enter/select the desired settings.
- Touch **Save** to save your settings.
- Touch **Cancel** to return to the previous screen without saving your changes.
- Touch **Reset** to undo entry and return to the default setting.
- Touch **Alt. Keys** or **Shift** to display extended characters (available characters will vary depending on Language setting).

Settings: Edit Tabs

Tab	Screen
Timers The ability to edit the settings of the TIMER tab varies by item and is defined with each item below. **IQC Interval (minutes)** – Edit on CM and RCU. Purpose: The interval between automatic IQC self-diagnostics. Range: 0 – 1440 minutes. Default: 0 (Disabled). **Menu Idle Timeout (minutes)** Edit on CM. Cannot be edited through RCU. Purpose: Amount of idle time before the 3M Rapid Detection Reader returns to the Home screen. Range: 1 – 10 minutes. Default: 5 minutes.	**Figure 28. Settings: Edit Timer Tab** 
File Edit on CM and RCU. Purpose: Define the locations for the device, group and time server settings. Please consult the local IT administrator and the online help for guidance on the use of these settings.	**Figure 29. Settings: Edit File Tab** 

Settings: Edit Tabs

Tab	Screen
Date/Time Edit on CM. Can only edit through RCU if NTP is enabled. Purpose: Set the current date and time for the 3M Rapid Detection Reader. If in Auto transfer Mode, the 3M Rapid Detection Reader date and time may be synchronized with the NTP server. The date format in the Reader is variable. To Change: 1. Use drop down menu to scroll through times zones and select correct time zone offset for your location. 2. Enter Current time. **NOTE:** When adjusting for changes in daylight savings time ensure the time zone offset is adjusted – not only the current time. **NOTE:** After changing the date or time, the CM power must be cycled to reset auto-IQC and data transfer timers. **NOTE:** The date format in the RCU is the same as for other applications running on that PC. **NOTE:** Periodically check that the clock is correct and has not been inadvertently changed.	**Figure 30. Settings: Edit Date/Time Tab** 
Language Edit on CM only. Purpose: Set the display language for the 3M Rapid Detection Reader.	**Figure 31. Settings: Edit Language Tab**
Misc. **Manual / Auto Transfer Mode** Edit on CM. Cannot edit through RCU. Manual Transfer Mode: 3M Rapid Detection Reader is set up for stand-alone operation. Auto Transfer Mode: 3M Rapid Detection Reader is set up for network operation. Default: Manual Transfer Mode.	**Figure 32. Settings: Edit Misc. Tab** 

Settings: Edit Tabs

Tab	Screen
Misc. *continued* **Sound** Edit on CM. Cannot edit through RCU. Test: Touch to hear indicator. On: The audio indicator is ON and sounds at the completion of an assay and when a USB device is connected or disconnected. Off: The audio indicator is OFF. Default: On There is no volume adjustment feature.	

Restoring Defaults

NOTE: Restoring device settings to factory defaults will erase all stored settings, assay results and operator information. Back up all device databases prior to restoring factory defaults. To transfer files from the 3M Rapid Detection Reader to another device, see Exporting Files.

1. From the **Settings** Menu (Figure 20), touch **Restore Defaults**. The **Settings: Restore Defaults** screen will open (Figure 33).
2. Touch **Restore Defaults** to restore factory defaults or **Cancel** to return the Settings menu.
3. After selecting Restore Defaults, a confirmation prompt will appear. Touch **Confirm** to restore defaults or **Cancel** to return to the settings menu.
4. When prompted, turn 3M Rapid Detection Reader off and on again to complete restoration of defaults.

Figure 33. Settings: Restore Defaults

Settings: Restore Defaults
! All Databases Will Be Erased
Back Up Files At Settings: Export Configuration
System Will Need To Be Restarted Following This Procedure
Restore Defaults
Cancel

Managing Operators

If an Operator ID or password is required, only individuals with Operator IDs stored on the 3M Rapid Detection Reader can perform assays and LQC, or select Menu options. The operator login requirements can be set on CM and RCU.

To access the Operator List on the Reader:

1. From the **Main Menu** screen (Figure 4), touch **Settings** and enter the Operator ID and Password (Figure 6).

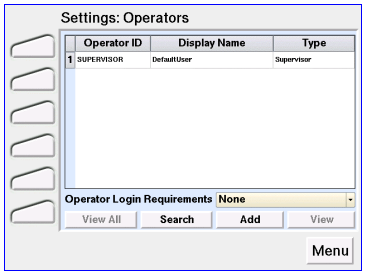
   The default login for access to the **Settings** menu is:

   Operator ID: **SUPERVISOR**

   Password: **PASSWORD**

   Both entries are case-sensitive

Figure 34. Settings: Operators



2. From the **Settings** menu (Figure 20), touch **Edit Operators**. The **Settings: Operators** screen will open (Figure 34).

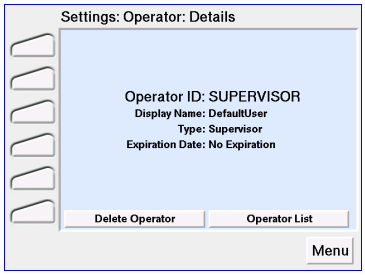
   A complete list of all operators authorized to use the device with Display Name and Operator Type is displayed.

   The 3M Rapid Detection Reader will store a maximum of 600 operators.

   The default Operator List includes the Operator ID defined as SUPERVISOR; the Display Name as DefaultUser; the Type set as Supervisor. This is the default login (see step 1 above).

   The **Operator Login Requirements** (Figure 34) determines if an Operator (Operator Type = Operator) requires an Operator ID and/or Password. The **Operator Login Requirements** can be set to None, Operator ID only, or ID and Password by selecting the € icon.

Figure 35. Settings: Operator Detail



   NOTE: The login requirements for operators (Operator Type = Supervisor) are defined and changed through the RCU. The default Login Requirements for Supervisors is ID and Password (Figure 25).

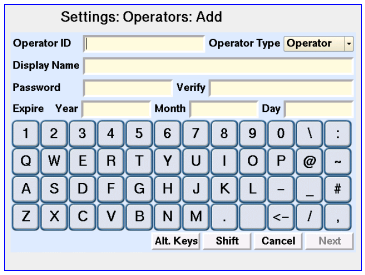
3. To view detailed information for an Operator, touch the Operator's entry and touch **View**.
4. To modify an existing operator, touch the Operator's entry and touch **Modify**. The **Add** button changes to **Modify**. (For additional instructions see Adding/Modifying an Operator.)
5. To add a new operator, touch **Add** when no operator entry is highlighted. (For additional instructions see Adding/Modifying an Operator.)
6. To search for a specific operator, touch **Search**. (For additional instructions see Searching for an Individual Operator.)
7. To delete an operator, touch **Delete Operator** while viewing an operator's details.

Adding/Modifying an Operator

The 3M Rapid Detection Reader will store a maximum of 600 operators.

Access the **Settings: Operators**: **Add** screen (Figure 36) as described above.

Figure 36. Settings: Operators: Add



To Add an Operator

1. Enter the Operator ID, Display Name, Password, Verify and, if desired, the Expire information.

   Operator ID: Characters entered to access 3M Rapid Detection Reader (Maximum length 18 characters).

   Display Name: Characters displayed with results for this Operator ID (Maximum length 50 characters).

   NOTE: Although 50 characters may be entered for a Display Name, the CM screen and print out will truncate. The full 50 character Display Name will only be visible in the Edit Operators screen in the Settings menu or through the RCU.

   Password: Maximum length 18 characters.

   Verify: Re-enter Password.

Expire: Date that operator's permission to use the 3M Rapid Detection Reader expires. Operator will be locked out after that date.

Disable expiration feature by leaving the field blank.

2. Use the € arrow to select the desired **Operator Type**: **Supervisor** or **Operator**.
3. Touch **Accept.** (The **Next** button changes to **Accept**.)
4. An entry verification screen appears. Select **Confirm** to add the operator information or **Cancel** to reject.

To Modify an Operator

If modifying an existing operator, the screen title will be **Settings: Operators: Modify** and the fields will be populated.

1. Modify the desired fields.
2. Touch **Accept**. (The **Next** button changes to **Accept**.)
3. An entry verification screen appears. Select **Confirm** to add the operator information or **Cancel** to reject.

Searching for an Individual Operator

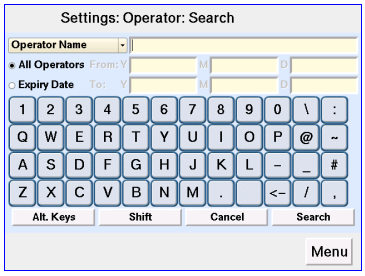
1. Access the **Settings: Operators: Search** screen (Figure 37) as described above.

   Settings: Operator: Search screen allows selection of operators by:

   - Operator Name
   - Operator ID
   - Expiry Date

2. To search for a specific Operator, select **Operator Name** or **Operator ID** using the € arrow and the drop down list. Enter the desired Name / ID to search.

Figure 37. Settings: Operator Search



Touch **All Operators** to disable expiry date fields for searching.

3. To search for operators whose permission to use the 3M Rapid Detection Reader expires in a given date range, touch **Expiry Date** and enter the date range.

   Default: from current date to current date + 10 years.

4. Touch **Search** or **Cancel**.
5. To return to the main list of operators, touch **View All**.

Editing Settings Using the Reader Configuration Utility (RCU)

Overview

The Reader Configuration Utility (RCU) allows the user to set up Readers according to the needs of their institution. The RCU stores this setup information in a set of Reader configuration files. Each Group of one or more Readers has its own directory containing a set of configuration files that define how the Readers in that Group operate. These files include assay lists and settings, LQC lists and settings and operator lists and settings. Note that more than one Group can share the same assay list, control list and/or operator list by either setting the list locations to the same directory for each Group OR by using **Save As** to save a list in multiple directories.

In a network environment, Readers can be set to periodically check their assigned Group directory for configuration changes. In addition, Readers can be configured to send new results and log information to a network directory.

In non-networked environments, a portable USB flash drive (supplied) is used to download the configuration files to the Reader and gather result and log files from the Reader. It is recommended that a separate USB flash drive should be used for configuring each Reader Group, this provides safe archive/restore functionality.

Complete instructions on the use of the RCU may be found in the RCU program under HELP or from the START menu under All Programs > Reader Configuration > Reader Configuration Manual.

Installation

The RCU is a software only product that can be installed on Client workstations running the Microsoft® Windows Operating System (2000/XP/Vista). Before beginning installation, be sure to have the necessary login privileges for installation of software on your workstation.

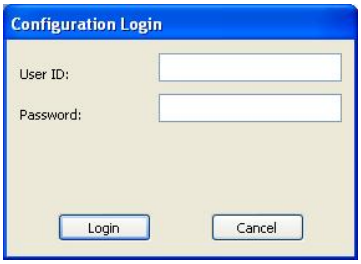
1. Insert the RCU CD into an available CD drive on your workstation.
2. A welcome menu should be displayed on your workstation.
3. Select “Install Reader Configuration Utility”.
4. Follow the on-screen prompts to complete the installation.

NOTE: If the installation does not auto-start, go to START>Run and type {CD drive}:install.hta <enter>.

Getting Started

Open the RCU from the START menu: All Programs >Reader Configuration> Reader Configuration Program (Figure 38).

Figure 38. Configuration Login



Login

When the RCU is initially installed, the default login is User ID: “Supervisor” and Password: “password” (case-sensitive). For increased security, it is strongly recommended to change these login details **immediately** to limit program access.

To change the default login

1. Select the **Settings** menu to open the **Reader Configuration: System Settings** screen (Figure 39).
2. Under Reader Configuration Utility Accounts, change the User ID, Account Name and Password.
3. Be certain that the Privilege level remains as Full Access.

   To save your settings select **File > Save**.

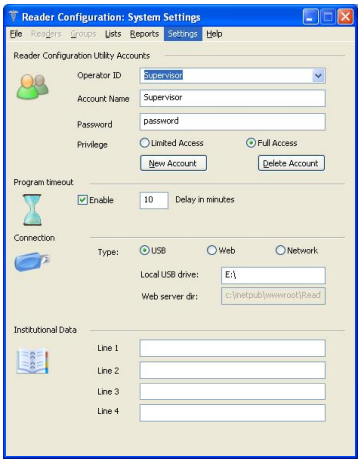
   New RCU accounts may also added from this screen. These accounts may be “Limited” or “Full Access”.

   “Limited Access" accounts only have access to the Controls Editor feature.

   "Full Access" users have complete access to all the program's functions.

   See the RCU Help for information on adding / editing and deleting users.

Figure 39. Reader Configuration System Settings: Settings



Emergency Password Reset Mechanism

If you forget your password, it may be temporarily reset to allow access to the encoded password list. To use this feature, type "**override**" in the User ID field of the RCU Login screen and select the "**Login**" button.

You will be presented with a message that says to contact Tech Support with a five digit number (Permit #). Please leave this prompt on the screen until you speak with your Technical Support Representative.

After receiving an override number, type this number into the "Password" field and click the "Login" button. You will have temporary access to the "Settings" screen, where you can view the user list and passwords.

NOTE: If the override number is entered incorrectly, it can be re-entered. If the number is entered incorrectly the second time, a new number is required.

Choosing a Configuration File Access Method

The RCU can be configured to access configuration files stored on a USB flash drive, a Network shared drive and/or a Web server.

Setting Up a USB Flash Drive

1. Select the **Settings** menu to open the **Reader Configuration: Systems Settings** screen (Figure 39).
2. Select the Connection type: USB.
3. Enter the “drive letter:” for the USB port that will be used.
4. Save your settings by selecting **File > Save** from the menu.

Setting Up Web Services Access:

1. Select the **Settings** menu to open the **Reader Configuration: Systems Settings** screen (Figure 39).
2. Select the Connection type: Web.

3. Enter the Web server directory. Contact the local IT administrator for the appropriate Web server directory.
4. Save your settings by selecting **File > Save** from the menu.

No additional setup is required to access configuration files on a network shared drive.

Accessing Configuration Files

A Group is defined as a common configuration shared by multiple Readers. As many Groups as necessary can be defined. Each Group MUST have its own Directory. A Directory contains a set of configuration files that define how the Readers in that Group operate. For example, one Group may be defined for Readers in an emergency department environment with files saved in a directory “ED”, while a separate set of configuration files, for use in an intensive care setting, would be defined in the Group “ICU” and saved in a directory “ICU”.

A default Group Directory (**C:\Program Files\Reader Configuration**) is set up during software installation. If only one group is needed, the initial files can be modified and saved in this directory.

If more than one group is needed, copy the default folder (C:\Program Files\Reader Configuration) and re-name or use the Save As command to save all files to a new directory. Each new folder **MUST** contain the following files: assays.dtv, controls.dtv, grp_settings.dtv, and, userlist.opl.

If transferring files by USB, all files in the Group Directory MUST be copied to the root directory of the USB.

CAUTION.

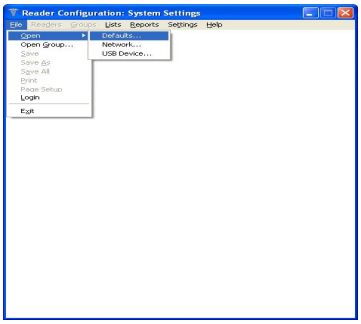
Do not change the file names.

To open all files for a group

Click **File > Open Group...**, select the folder containing the files to be used and click **OK**. If only one group is being used, the default location is C:\Program Files\Reader Configuration\. This will open the following files: group settings, userlist, controls and assays.

Detailed information on the use of the RCU files can be found in the RCU HELP sections.

Figure 40. Reader Configuration System Settings: File



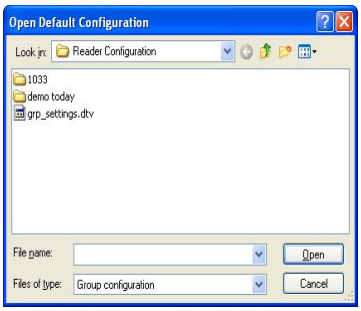
To open an Individual Configuration File

If only one configuration file requires modification, for example, when updating Operator Lists, there is no need to open all the Group files, just the file to be changed (in this example, userlist.opl). To do this, click on **File > Open**, and then select **Defaults...**, **Network...** or **USB Device...**.

A "File Open" screen will display allowing navigation to the drive containing the files of interest (Figure 41).

To select different types of files to load, select the **Files of Type** dropdown list. As each file type is selected, a list of those files present in the currently selected directory will be made available. Select the desired file name and then click **Open**.

Figure 41. Open Default Configuration



Setting Up Communications Between RCU and Readers

In the RCU: Open the default **Group Settings** file (Figure 42).

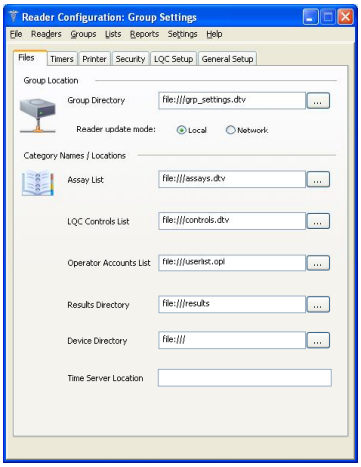
Files

This page sets the file locations where the Reader(s) looks for specific configuration information. The Reader supports the HTTP, HTTPS, FTP and FTPS file transfer protocols. Directories are specified in URL notation. Please consult the local IT administrator for guidance on the use of these settings in the local network environment. If Readers will use the USB flash drive for configuration information, all file location fields should be set to: file:/// as in the default settings (except time server, which should be blank).

Examples of supported configurations are listed below.

- USB Flash drive: "file:/// "
- Web Server: "http://medsvr/3M Rapid Detection Reader/ "
- Network drive: "ftp://fileserver/3M Rapid Detection Reader_share/"

Figure 42. Reader Configuration: Group Settings



The **Group Directory** field identifies where the Reader(s) looks for all group specific information.

The **Assay List** field identifies where the Reader(s) looks for its list of supported assays.

The **LQC Controls List** field identifies where the Reader(s) looks for its list of LQC controls.

The **Operator Accounts List** field identifies where the Reader(s) looks for its operator list.

The **Results Directory** field identifies where the Reader(s) places exported result files. In a networked environment one or more groups can share the same destination directory.

The **Device Directory** field identifies where the Reader(s) should read and write device specific information – this is typically set to the same directory as the Group Directory.

The **Time Server Location** allows the Reader group to access an NTP (Network Time Protocol) server to keep the Reader's internal clocks set to the correct time. This field should be left blank in non-networked environments or networked environments that lack access to an NTP server.

Identifying Readers through the RCU

The RCU uses Reader information files to identify the Readers installed within an institution. Once a Reader has been identified, the RCU may be used to change Reader specific settings.

Non-networked Environment

A USB flash drive is used to transfer Reader settings between the Reader and the RCU. It is recommended that the USB flash drive provided with the 3M Rapid Detection Reader is used as it is pre-configured with the appropriate folders.

1. Insert a USB flash drive in an available USB port on the CM. Ensure that the USB drive contains four folders named: lqc, patient, iqc, log.
2. Navigate to the Reader Settings screen and touch **Export Configuration**.
3. Touch **Export to USB Flash Drive**.
4. All settings files and result logs are exported.
5. Steps 1 to 3 can be repeated for additional Readers, if desired.
6. Insert the USB flash drive into the RCU computer's USB drive.
7. From the RCU, click on **File > Open**, select **USB Device** (navigate to the correct location of the USB Device if this function does not work automatically). Select the **Files of Type – Readers.** Select the desired Reader Serial number and then click **Open**.
8. Changes to settings for the selected Reader may now be defined on the Reader Settings menu.

For more information see **Importing Files** or **Exporting Files** below.

Networked Environment

Each Reader must be placed into network mode and must be assigned a device information directory prior to successful bi-directional communications.

1. Using the Reader Touch screen, navigate to the Reader **Settings: Edit Settings: File** screen (Figure 29).
2. Enter the Device and Group Directory Settings for the Reader as defined in the RCU.
3. Navigate to the Reader **Settings: Edit Settings: Misc** screen (Figure 32) and enable Auto Transfer mode.
4. From the RCU, click on **File > Open**, and then select **Auto Transfer Mode**. Select the **Files of Type – Readers.** Browse to the device directory for the Reader of interest, select the desired Reader serial number and then click **Open**.

Settings for the selected Reader may now be defined on the Reader Settings menu.

For detailed information on all the RCU functions, refer to the Help Menu in the RCU program.

Importing Files

Device settings, including Operator Lists from the RCU or another 3M Rapid Detection Reader, can be imported using the USB flash drive.

1. From the **Settings** menu (Figure 20), touch **Import Configuration**. The **Settings: Import Configuration** screen opens (Figure 43).
2. Insert the USB flash drive into an available USB port.
3. Touch the files required, touch **Transfer.**

   Transfer is indicated by blue circles across the bottom of the screen. If necessary, touch **Cancel** to stop the transfer.

   A Transfer Complete notification (Figure 44) is displayed when transfer is finished. Touch **OK** to return to the **Settings** menu.

   If Transfer fails, the warning icon is displayed. (Refer to the Troubleshooting Section.)

Figure 43. Settings: Import Configuration

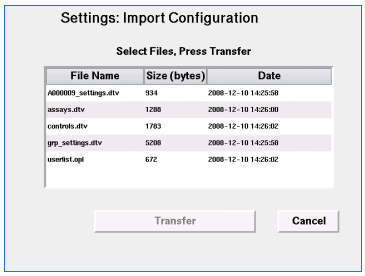
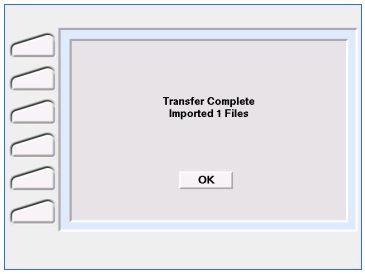


Figure 44. Settings: Import Configuration Transfer Complete



Exporting Files

Exporting files allows back-up of critical information from the 3M Rapid Detection Reader including configuration files, operator lists and results files. Back-ups should always be created prior to relocating the 3M Rapid Detection Reader.

1. From the **Settings** menu (Figure 20), touch **Export Configuration.** The **Settings: Export Configuration** screen opens (Figure 45).
2. Insert the USB flash drive into an available USB port.

   Touch **Export to USB Flash Drive**.

   NOTE: The Flash Drive must be pre-configured with 4 subdirectories (folders) named: patient, lqc, iqc and log (case-sensitive).

   Transfer is indicated by blue circles across the bottom of the screen. Eleven files are transferred (listed in Figure 45, All Results includes 3 files).

   A Transfer Complete notification (Figure 46) is displayed when transfer is finished. Touch **OK** to return to the **Settings** menu.

   If Transfer fails, the warning icon is displayed. (Refer to the Troubleshooting Section.)

Figure 45. Settings: Export Configuration

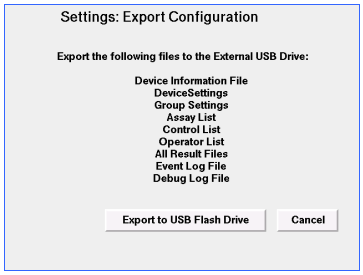
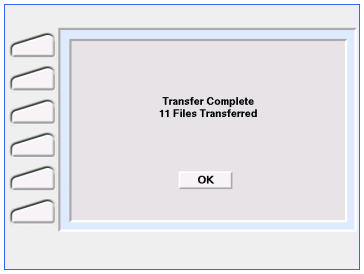


Figure 46. Settings: Export Configuration Transfer Complete



Deleting Results

The 3M Rapid Detection Reader can store up to 900 results (300 patient, 300 LQC and 300 IQC) and 500 events (log file entries). When the CM database is full, the oldest result is over-written.

In Manual Transfer mode only (*i.e.,* when 3M Rapid Detection Reader is not connected to a network), the warning "Database Almost Full, Backup Data" will be displayed when the patient or QC result databases have less than 20 spaces left. No warning is displayed when the event log is full.

NOTE: Prior to deleting results, transfer and store all data in accordance with applicable local, state and/or federal guidelines or accreditation requirements and each facility's protocol.

In Auto Transfer mode, only new results that have not been previously transferred are transferred during an upload. Data is not deleted from CM upon transfer.

1. From the **Settings** menu (Figure 20), touch **Delete Results**. The **Delete Results** screen will open (Figure 47).
2. Touch **Delete All Results** or **Delete Results Prior to Date**.

   Delete All Results:

   Touch **Confirm**.

   Delete Results Prior to Date:

   Enter the desired date (Figure 48), touch **Confirm**.

   Once Results Deleted message is displayed, touch **OK** to return to the **Settings** menu.

Figure 47. Settings: Delete Results

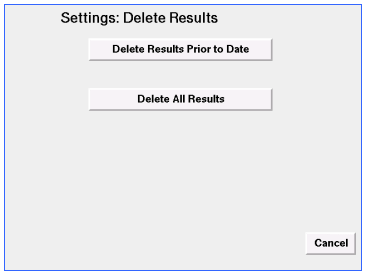
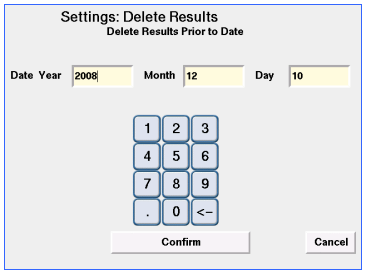


Figure 48. Settings: Delete Results Prior to Date



Maintenance

WARNING!

To reduce the risk associated with hazardous voltage:

- Unplug the 3M Rapid Detection Reader before cleaning.
- Do not disassemble the 3M Rapid Detection Reader or any of its related components and accessories. The instrument contains no operator-serviceable components.
- Do not immerse any of the 3M Rapid Detection Reader components in any liquid.
- Do not use the 3M Rapid Detection Reader if there is apparent damage to a power cord or power supply.

To reduce the risk associated with potentially infectious patient samples:

- Do not spill specimen or sample fluids on any of the 3M Rapid Detection Reader components or on the outside of the Test Cartridge.
- If a spill occurs, disinfect external surfaces only, using a soft cloth containing a solution of 0.5% bleach, 70% isopropyl alcohol or 70% ethanol.

The 3M Rapid Detection Reader requires no regular maintenance or calibration during its intended life span, other than exterior cleaning as needed.

Any liquids on the external surface of a Test Cartridge must be cleaned before inserting into the ports of the TM.

Exterior Cleaning

CAUTION.

To reduce the risk of instrument or accessory damage:

- Do not immerse the 3M Rapid Detection Reader or related devices in any liquid.
- Do not spill liquids on the 3M Rapid Detection Reader and related accessory devices.
- Do not expose the 3M Rapid Detection Reader to temperatures above 60°C (140°F). Do not disinfect or sterilize the 3M Rapid Detection Reader using devices such as autoclaves, ultrasonic cleaners, or pasteurizers. Use of such methods to disinfect/sterilize the 3M Rapid Detection Reader will cause permanent device damage and void the warranty.

The external surfaces of the TM and CM can only be disinfected using a solution of 0.5% bleach, 70% isopropyl alcohol or 70% ethanol applied to a soft cloth.

CAUTION.

Possible device damage:

- DO NOT USE STRONG BLEACH (>0.5% solution) OR ACETONE! Oxidants and solvents could damage the 3M Rapid Detection Reader casing and touch screen.
- Clean external surfaces only.

If the 3M Rapid Detection Reader requires repair or replacement, it must be disinfected prior to repackaging and shipping.

Upgrading Device Software

In the event there are enhancements made to the 3M™ Rapid Detection Reader software, upgrades will be available through a USB Flash Drive. Attach the drive containing the latest software to the CM and follow the instructions provided with the USB and those below.

1. From the main **Settings** menu (Figure 20), touch **Upgrade**. The **Settings: Upgrade** screen will open (Figure 49).
2. Touch the appropriate selection:
   - **Upgrade All Software**: upgrades CM software only.
   - **Upgrade Port Software**: upgrades the TM only
   - **Upgrade Languages Only**: upgrades language software
   - **Cancel**: returns to the Settings menu without upgrade
3. Touch **Confirm** to confirm software upgrades (Figure 50) or **Cancel** to return to **Settings** menu.
4. When prompted, turn 3M Rapid Detection Reader off and on again to complete the upgrade.

Figure 49. Settings: Upgrade

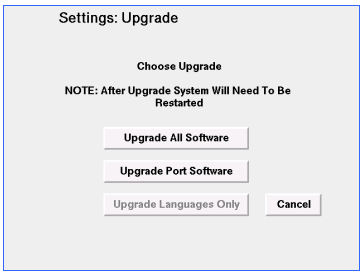
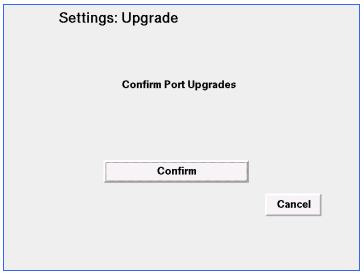


Figure 50. Settings: Upgrade Confirmation



Disposal of Equipment

Do not dispose of this product in municipal waste. Please contact your local 3M subsidiary to arrange disposal and recycling.

Troubleshooting

The following information is to be used to diagnose and resolve general errors and error messages displayed by the CM. If additional assistance is needed, please contact 3M Health Care Helpline.

3M Health Care Helpline - 1-800-228-3957

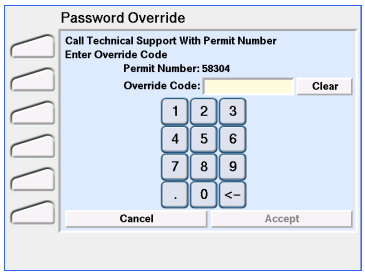
Outside the U.S.A. and Canada, contact your local 3M subsidiary.

Restoring the Supervisor Operator ID / Password

By default, only a Supervisor with a correct ID and password can access the **Settings** menu. The default login is Operator ID: **SUPERVISOR**, password: **PASSWORD**. Both entries are case-sensitive. If the login has been changed, the password is lost, and login fails, the user can override and access the **Settings** menu.

1. From the **Operator ID Entry** screen (Figure 6), type OVERRIDE in Operator ID field. Touch **Next**.
2. The **Password Override** screen (Figure 51) will open, prompting the user to contact Technical Support with the displayed permit number.
3. Technical Support will provide the user with an Override Code that must be entered into the Override Code field.
4. Touch **Accept**. The CM verifies the Code and restores the factory default. Operator ID: SUPERVISOR, Password: PASSWORD.

Figure 51. Password Override



5. Touch **OK**.
6. The screen returns to the **Settings** menu (Figure 20), touch **Edit Operators** to go to the **Operators** screen (Figure 34).

   Touch **Default user** with Operator ID: SUPERVISOR from the Operator list, touch **Modify** to change the Operator ID, Display Name, Password and Expiration Date.

General

Symptom	Action
The CM touch screen is hard to read (very dim), or colors are not visible.	Contact Technical Support to report the problem.
CM does not turn on or light up.	Check if cable connections are loose. Check system power; ensure power supply is connected. If problem persists, contact Technical Support to report the problem.
TM is not recognized by CM.	Check if connections are loose. Switch the CM off and switch back on. If problem persists, contact Technical Support to report the problem.

Power On Self Test Message / IQC Messages

Message	Cause	Action
No Available Ports. IQC Failed To Start.	Ports are disabled.	All ports are disabled. Switch the CM off and switch back on. If problem persists contact Technical Support to report the problem.

Test Run Messages

To display the error message, before removing the cartridge, touch the red port icon for detailed information about the failure. Once the cartridge is removed, this information is sent to the appropriate Log files. Refer to Viewing Saved Logs for additional information.

Test Run Messages – indicated by red port icon

Port Display	Error Message	Cause (s)	Action
CTG	Cartridge Error	Possible defect in Test Cartridge.	The Test Cartridge is ejected. Remove and dispose of appropriately. Repeat the assay with a fresh set of components. If problem persists contact Technical Support to report the problem.
HRB	High Background	Possible interfering substances in the sample causing high running background.	
LOW	Low Signal	Insufficient sample transferred to the Test Cartridge. Insufficient mixing of the sample with the supplied assay tip. Interfering substances in the sample.	
Fail	Sample Error 1	Sample flow occurred before the Test Cartridge was inserted into the port. Delay of more than 30 seconds between sample addition and Test Cartridge insertion. Insertion of a used Test Cartridge.	

Test Run Messages – indicated by red port icon

Port Display	Error Message	Cause (s)	Action
Fail	Sample Error 2	Sample flow has not been detected. Insufficient sample added to the Test Cartridge. Clogged sample pad. Failure to use supplied assay tip. Insufficient mixing of sample. Interfering substances in the sample. Analyte levels significantly higher than the upper reportable range.	The Test Cartridge is ejected. Remove and dispose of appropriately. Repeat the assay with a fresh set of components. If problem persists contact Technical Support to report the problem.
Fail	Temperature Error	TM not at proper temperature to carry out specific assay requested.	Contact Technical Support to report the problem.
Error XX *e.g.*, Error 2B	Port Disabled	The identified port is disabled due to failing IQC or a transport carriage failure. LED remains illuminated red.	Contact Technical Support to report the problem.

Test Run Messages

Message / Symptom	Cause	Action
Insertion Error Remove & Reinsert **Followed by:** **Timed Out**	The Test Cartridge was not inserted properly into the 3M Rapid Detection Reader or the operator did not wait until prompted. User has not performed the action required within time period allowed.	Cancel the assay or reinsert the Test Cartridge. Fully insert Test Cartridge until firm resistance is felt. Do not use excessive force. The TM will guide the Test Cartridge into the port. **NOTE:** The Test Cartridge must be reinserted into the TM port within approximately 30 seconds or an error message will be displayed and the assay will be aborted. Repeat assay using a fresh set of components.

Test Run Messages

Message / Symptom	Cause	Action
Barcode Error Aborting Assay	The 3M Rapid Detection Reader was unable to read the barcode on the Test Cartridge.	Repeat assay using a fresh set of components.
No Ports Available, Assays in Progress	All ports are in use by other assays.	Touch **OK** to return to the main menu and wait until an assay is complete before attempting to run another test.
No Ports Available, Remove Cartridge(s) Try Again	Cartridges occupying all ports	Remove Test Cartridge(s) for completed assay(s).

Lot Card Messages

Message / Symptom	Cause	Action
No response to insertion of a Lot Card.	Lot Card Assembly not functioning.	Contact Technical Support to report the problem.
Lot Card Error, Reinsert	The 3M Rapid Detection Reader was unable to read the Lot Card correctly. The Lot Card may have been removed too quickly, or not fully inserted into the Lot Card slot.	Touch **OK**, then reinsert the Lot Card. If the problem persists use a Lot Card from another box of Tests with the same Lot number. If another Lot Card is not available or alternate lot card fails, contact Technical Support.
Lot # XXX Not Found, Insert Lot Card or Cancel	The 3M Rapid Detection Reader does not contain the data required to run Test Cartridges with that Lot # The Lot Card for this Test Kit Lot may not have been inserted before running the assay.	Insert the Lot Card for the specified lot or cancel assay. **NOTE:** The correct Lot Card must be inserted within approximately 30 seconds or the assay will be aborted. Repeat assay using a fresh set of components.
Lot Card Expired	The Lot Card inserted has expired. Expiry falls on the last day of the month.	Check the date/time settings within the 3M Rapid Detection Reader. Use components that have not expired.

Settings Messages

Message	Cause	Action
Access denied. Try again.	The user does not have the login permissions necessary to access selected function.	Confirm correct login details and try again.
Assay List Size Exceeded.	The list of assays permitted is full. No further additions can be made.	Delete existing assays from the assay list (Refer to RCU online help). The maximum number of assay entries allowed is 200.
Assay Locked, Aborting.	The assay is not permitted or has been locked. May occur if LQC has failed or assay is not in the assay list.	Contact Supervisor or RCU Full Access User for more information.
Database Almost Full, Backup Data	Displayed when the3M Rapid Detection Reader is not connected to a network and either the patient or LQC result databases has less than 20 spaces left. This message will continue to be displayed until the database is cleared.	Transfer data to USB device and delete the database.
Default Restore Failed.	The action to restore defaults has failed.	Try this process again. If problem persists contact Technical Support.
ERROR: Invalid Code. Try Again.	The override code entered is invalid.	Contact Technical Support, then enter the override code provided.
ERROR: Numbers Only.	Only numbers are permitted in the override code field.	Enter the number provided by Technical Support.
Invalid Password, Try Again.	The password was incorrectly entered.	Retype the password and try again.
Invalid User, Try Again.	The user is not recognized or has been entered incorrectly.	Retype user details and try again.
Locked, Contact Supervisor.	The 3M Rapid Detection Reader has been locked via the RCU.	Contact the RCU Full Access User to unlock using the Reader Settings screen.
Empty Search.	The 3M Rapid Detection Reader cannot find the record requested. It may have been deleted or details entered incorrectly.	Re-enter search data and try again.

Settings Messages

Message	Cause	Action
User Expired, Try Again	User certification has expired or the details were entered incorrectly.	Re-enter Operator ID or contact Supervisor.

LQC Related Messages

Message	Cause	Action
LQC Lockout. Ejecting.	LQC is overdue for this assay and no overrides are available.	LQC must be run and passed, or a Full Access User can reset the LQC timer and/or overrides for this assay in Reader Settings on the RCU.
Invalid Control. Ejecting.	Control ID does not exist for this assay or has been entered incorrectly.	Repeat LQC with correct Control ID or contact Supervisor.
LQC Overdue, Assays Locked	LQC has expired and all available overrides have been used. Tests cannot be run until the required LQC has been run and passed.	Run the required LQC.
	LQC will be due shortly. Appears when the LQC timer for an assay has less than the user defined % of time remaining until lockout.	Run the required LQC.
	LQC has expired for one or more assays. If icon is displayed, the **Assay Status Warnings** screen (Figure 11) will display upon touching the **Run Assay** button.	Run the required LQC. A limited number of overrides can be configured via the RCU. If overrides are available, touch **Continue** to override lock out (*i.e.,* perform a patient test after LQC is due). The decision to use an Override will be confirmed (Figure 12). Once all overrides have been used, LQC must be performed prior to any further patient testing. If an assay with no overrides is inserted into the TM, an LQC Overdue, Assay Locked warning will display and the assay will be aborted.

Warnings and Confirmation Requests

Message	Cause	Action
! All Databases Will Be Erased **Back up files at Settings: Export Configuration** **System will restart following this procedure**	Request was made to upgrade software or reset system to default settings.	Cancel if not intended. Before performing this operation all databases should be backed up using Export Configuration
! All Results Will Be Deleted	Request was made to delete all results.	
ERROR - Missing Firmware Version File	The file required to complete the upgrade is missing.	Contact Technical Support
ERROR - Upgrade Failed **Restart to Try again**	Upgrade failed.	Restart 3M Rapid Detection Reader and re-try upgrade. If problem persists contact Technical Support.

Printer Errors

Message / Symptom	Cause	Action
Printer Error 	3M Rapid Detection Reader is not able to communicate with printer. Printer may be offline.	Reconnect printer, switch on and try again. If printer is not being used turn off Auto Print via RCU. Refer to RCU help manual for details.
Poor print quality	Poor print quality maybe due to use of wrong print labels or print ribbon.	Refer to Printer Manual. Consumables required for printer: Labels: 2.25” W x 3” L Z-Select 4000T labels from Zebra® Technologies· Ribbon: 57mm x 74m Wax/Resin Ribbon from Zebra® Technologies
Failure to print	Poor cable connection or jammed printer.	Check if cable connections are loose. Check if printer is jammed; refer to Printer Manual for instructions. If problem persists contact Technical Support to report the problem.

Printer Errors

Message / Symptom	Cause	Action
Printer light does not turn on	Printer is not receiving power.	Refer to Printer Manual. Check system power; ensure power supply is connected. Ensure that switch on bottom right side of the printer is turned to the ON position. If problem persists contact Technical Support to report the problem.

Communications Errors

Message	Cause	Action
Transfer Error	Network communications error, or error writing to USB flash Drive.	Check all connections and try again. Ensure that the USB is pre-configured with the four required directories: patient, lqc, iqc and log. If problem continues, contact Supervisor or Technical Support.
Transfer Failed		

USB Device Errors

Message	Cause	Action
Multiple Printers Attached, Remove Device	Two USB printers are connected. Only one printer is permitted.	Remove additional printer.
Multiple USB Drives attached, Remove Device	More than one USB device of the same type is connected.	Remove the additional USB device. Leave one connected.
Unrecognized Scanner or Keyboard, Remove Device	Device attached not supported by 3M Rapid Detection Reader.	Remove device. **NOTE**: Barcode Scanner must be configured for HID keyboard emulation. (Refer to Scanner Quick Start Guide.) If problem persists, contact Technical Support.
USB Not Visible. Reinsert & Try Again	The USB device is not detected by the 3M Rapid Detection Reader.	Re-connect the USB device and try again.

USB Device Errors

Message	Cause	Action
Unrecognized USB Drive Attached, Remove Device	A USB drive without a valid partition table is inserted into the CM.	Use the USB drive supplied with the 3M Rapid Detection Reader

Specifications

CAUTION.

Possible device damage and warranty invalidation. Changes or modifications to this equipment, not expressly approved by the manufacturer could void the warranty.

TM Specifications	
Model Name	3M 3968
Dimensions	185mm D x 195mm W x 96mm H
Weight	1.5kg
External connections	(1) RS485 - TM to CM

CM Specifications	
Model Name	3M 3960
Dimensions	177mm D x 195mm W x 105mm H
Weight	1kg
Input Power Requirements	12 V DC, 120 W
Power supply	100 - 240 VAC, 50-60 Hz
Power cord length	4 ft (1.22 m) min from power supply to CM
Power supply input connector	IEC 320 C14 compatible
Power supply standards	Certified for CE, CSA, UL, C-Tick, according to intended regions. Conforms to WEEE requirements.
External Connections	USB 2.0 and 1.1 (3 available), RJ-45 Ethernet, Serial RS-485 (3 available),
Ethernet Connectivity	TCP/IP, DHCP dynamic IP addressing, SSL over TCP, HTTP, HTTPS, FTP, FTPS
Controls	On/Off toggle switch. O = off / I = on. Touch screen: VGA LCD alpha-numeric display, accepts input from bare finger, latex or nitrile gloved finger, or stylus. Touch screen buttons: Main Menu, Run Assay, Run LQC, IQC, Results, Settings, Operator List, Cartridge status area (6).

CM Specifications	
Supported USB Devices	Label printer: Zebra® TLP 2824 Generic USB flash drive Barcode scanner: Symbol Technologies LS9208.
Display	640 x 480 pixels, 5.7~6.5 " diag (14.48~16.51 cm diag).

TM / CM Specifications	
Operating temperature	15 - 30º C (59 - 86º F)
Storage temperature	-10 - 50º C (14 - 122º F)
Operating Humidity	20 – 90% relative humidity, non-condensing.
Operating/Storage Elevation	0 – 2000m
Complies with:	United States: Title 47 CFR Part 15; Canada: Title 47 CFR Part 15 or IEC 61326; European Union: IEC 61326; Australia: IEC 61326; Japan: IEC 61326; China: IEC 61326.
Complies with the following IEC Standards:	UL/IEC 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use. UL/IEC 61010-2-010 - Particular requirements for laboratory equipment for the heating of materials. UL/IEC 61010-2-081 - Particular requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes. UL/IEC 61010-2-101 - Particular requirements for in vitro diagnostic laboratory (IVD) equipment. UL/IEC 60529 - Degrees of protection provided by enclosures. UL/IEC 60825-1 - Safety of laser products - Part 1: Equipment classification, requirements, and user guide.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

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